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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,487	01/25/2002	Lisa A. Racie	08702.0073-00000	3565

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[REDACTED] EXAMINER

SLOBODYANSKY, ELIZABETH

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1652

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DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/057,487	RACIE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
Elizabeth Slobodyansky	1652		
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>Period for Reply</b>			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
<p>1)<input type="checkbox"/> Responsive to communication(s) filed on _____.</p> <p>2a)<input type="checkbox"/> This action is <b>FINAL</b>.                  2b)<input type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>			
<b>Disposition of Claims</b>			
<p>4)<input type="checkbox"/> Claim(s) <u>1-27</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input type="checkbox"/> Claim(s) _____ is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input checked="" type="checkbox"/> Claim(s) <u>1-27</u> are subject to restriction and/or election requirement.</p>			
<b>Application Papers</b>			
<p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner.</p> <p style="margin-left: 20px;">Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p>			
<p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner.</p> <p style="margin-left: 20px;">If approved, corrected drawings are required in reply to this Office action.</p>			
<p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
<p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> <li>1.<input type="checkbox"/> Certified copies of the priority documents have been received.</li> <li>2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</li> <li>3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> <p>* See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p>			
<p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>			
<b>Attachment(s)</b>			
<p>1)<input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.</p>		<p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____.</p>	

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## DETAILED ACTION

This application is a continuation-in-part of copending application 09/978,979.

Claims 1-27 are pending.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 5 (in part), 6-10 and 12, drawn to a DNA of SEQ ID NO:2 and a complement thereof, a vector containing said DNA, a cell transformed with said vector and a recombinant method for producing an aggrecanase, classified in class 435, subclass 212.
- II. Claims 3, 5 (in part) and 27 (in part), drawn to a DNA of SEQ ID NO:4, classified in class 536, subclass 23.5.
- III. Claims 4, 5 (in part) and 11, drawn to a DNA of SEQ ID NO: 7 and a recombinant method for producing an aggrecanase, classified in class 435, subclass 212.
- IV. Claims 13 and 15, drawn to an aggrecanase of SEQ ID NO:1, classified in class 435, subclass 212.
- V. Claims 14 and 16, drawn to an aggrecanase of SEQ ID NO:8, classified in class 435, subclass 212.

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- VI. Claim 17, drawn to an antibody against an aggrecanase of SEQ ID NO:1, classified in class 530, subclass 387.1.
- VII. Claim 18, drawn to an antibody against an aggrecanase of SEQ ID NO:8, classified in class 530, subclass 387.1.
- VIII. Claims 19, 21 and 23, drawn to methods of computer aided analysis of protein sequence of SEQ ID NO:1, classified in class 700, subclass 98.
- IX. Claims 20, 22 and 24, drawn to methods of computer aided analysis of protein sequence of SEQ ID NO:8, classified in class 700, subclass 98.
- X. Claim 25, drawn to an inhibitor of aggrecanase, classified in class 530, subclass 300.
- XI. Claim 26, drawn to an *in vivo* method of use an inhibitor of aggrecanase, classified in class 530, subclass 300.
- XII. Claim 27 (in part), drawn to a protein encoded by SEQ ID NO:4, classified in class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XII are patentably distinct because a DNA, a protein, an antibody and an inhibitor, are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of inventions I-III are not

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limited in use for the production of aggrecanases of inventions IV, V and XII and can be used as hybridization probes, and aggrecanases of inventions IV, V and XII can be obtained by a materially different method such as by the biochemical purification or chemical synthesis. While aggrecanases of inventions IV and V are related to antibodies of inventions VI and VII, respectively, as being cognate antigens, the structure of antibodies is unpredictable from the structure of the protein of inventions IV and V. Further, antibodies of inventions VI and VII may cross-react not only with an aggrecanases of inventions IV and V but with other proteins. Aggrecanases have other utility besides acting as antigens to induce the antibodies such as for the methods of Groups VIII and IX. An inhibitor of invention X is structurally and functionally different from aggrecanases of inventions IV and V and antibodies of inventions VI and VII and can affect various enzymes.

Inventions (I-III), (IV, V, XII) and (VI and VII), respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides, the polynucleotides encoding them and antibodies against them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

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Inventions (IV and VIII) and (V and IX), respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used to induce antibodies and in *in vitro* screening for inhibitors thereof.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used to induce antibodies.

Inventions VIII, IX and XI are patentably distinct because they are drawn to materially different methods employing different products such as different aggrecanases and inhibitors.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

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A telephone call was made to Ms. Carol Cole on February 5, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

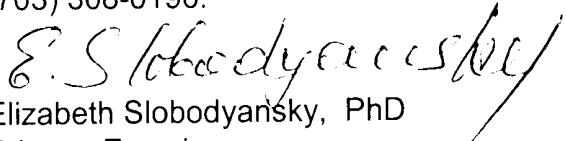
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

  
Elizabeth Slobodyansky, PhD  
Primary Examiner  
February 13, 2003